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CureVac to Shift Focus of COVID-19 Vaccine Development to Second-Generation mRNA Technology

CureVac N.V., a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced the strategic decision to focus its COVID-19 vaccine development towards the development of second-generation mRNA vaccine candidates in collaboration with GSK and to withdraw its first-generation COVID-19 vaccine candidate, CVnCoV, from the current approval process with the European Medicines Agency (EMA).

In view of a recent EMA communication, CureVac estimates that the earliest potential approval of CVnCoV would come in the second quarter of 2022. By this time, the companies expect the candidates from the second-generation vaccine program to have progressed to late-stage clinical development. The decision is also aligned with the evolving dynamics of the pandemic response towards a greater need for differentiated vaccines to address the developing endemic SARS-CoV2 situation. As a direct consequence, the existing Advanced Purchase Agreement with the European Commission, which was predicated on employing CVnCoV to address the acute pandemic need, will cease. CureVac is assessing the possibility of leveraging CVnCoV commitments for the second-generation vaccine candidates. CureVac remains in contact with the European Commission and is supportive of its public health efforts.

CureVac and GSK have tightened their collaboration by adding further resources and experts to accelerate development and manufacturing of the broad second-generation program. The companies anticipate entering clinical development in the next months, aiming to achieve regulatory approval for market readiness of an improved COVID-19 vaccine in 2022. Published pre-clinical results have shown the strong potential of the initial second-generation mRNA COVID-19 vaccine candidate, CV2CoV, compared to CureVac's first generation mRNA, CVnCoV. The data demonstrates up to 10x higher immunogenicity in animal models. In parallel to the work on the second-generation mRNA vaccine technology, GSK and CureVac will accelerate efforts to progress the development of modified mRNA vaccine constructs.

"The global fight against COVID-19 continues, and we remain committed to making a difference with a safe and efficacious vaccine. This goal has not changed, but the requirements to effectively address the virus and emerging variants have changed. In the ongoing transition from acute pandemic to endemic, our decision to withdraw CVnCoV from the regulatory approval process and focus our efforts on second-generation mRNA vaccine candidates reflects expected changes in public health needs that our second generation can potentially address," said Franz-Werner Haas, Chief Executive Officer of CureVac. "We will now take advantage of CVnCoV learnings and infrastructures to focus our resources on advanced second-generation vaccines in close collaboration with GSK, a global leader in the vaccine field."

Rino Rappuoli, Head of Vaccines R&D, GSK said: "We welcome CureVac's focus on the promising second-generation mRNA vaccine technology we are developing together as it has shown strong improvement compared to CureVac's first-generation candidate, CVnCoV, in pre-clinical testing. To complement the development of this second generation non-modified mRNA technology, we have also initiated the development of modified mRNA technologies as part of our collaboration."

The CureVac-GSK COVID-19 collaboration builds on the existing strategic mRNA technology partnership both companies started in July 2020 for several selected targets in the field of infectious diseases. The collaboration was recently extended, allocating additional resources across both companies. The joint development focuses on optimized second-generation mRNA vaccines that offer the potential to target different COVID-19 variants, the ability to address different diseases in a combination shot and improved vaccine administration formats.

About CureVac

CureVac is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing and optimizing this versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of optimized mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. In July 2020, CureVac entered in a collaboration with GSK to jointly develop new products in prophylactic vaccines for infectious diseases based on CureVac's second-generation mRNA technology. This collaboration was later extended to the development of second-generation COVID-19 vaccine candidates, and modified mRNA vaccine technologies. Based on its proprietary technology, CureVac has built a deep clinical pipeline across the areas of prophylactic vaccines, cancer therapies, antibody therapies, and the treatment of rare diseases. CureVac had its initial public offering on the New York Nasdaq in August 2020. It is headquartered in Tübingen, Germany, and employs more than 700 people at its sites in Tübingen, Frankfurt, and Boston, USA. Further information can be found at www.curevac.com.

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Further information

CureVac Investor Relations Contact:
Dr. Sarah Fakih
Vice President Corporate Communications and Investor Relations
CureVac, Tübingen
Phone: +49 (0) 7071 9883 1298
E-mail: sarah.fakih(at)curevac.com

CureVac Media Contact:
Anna Kamilli
Manager Communications
CureVac, Tübingen
Phone: +49 (0) 7071 9883 1684
E-mail: anna.kamilli(at)curevac.com

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